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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John P. Peeters

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EXAMINER

MEHMOOD, JENNIFER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,901	Applicant(s) PEETERS, JOHN P.	
	Examiner JENNIFER MEHMOOD	Art Unit 2612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14, 16, 18-20, 22-25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 30-34, 38-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14, 16, 18-20, 22-25, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 8, 9, 11, 13, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114) and further in view of Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609).

For claim 1, Crowley discloses a diagnostics system comprising: a patch having an adhesive portion adapted to stick to the skin of a human subject (col 10, Ins 10-20; Fig. 2, item 68); a radio frequency identification tag (RFID) (col 4, Ins 14-20; col 7, Ins 51-60); and a sensor module integrated with said patch, said patch further having an antenna (Fig. 1, item 42), an RFID chip (col 5, Ins 15-17; col 7, Ins 61-65), and at least one sensor associated with a unique identification code (col 4, Ins 14-20), said RFID and sensor module responding to a biological stimulus by wirelessly transmitting through the use of said antenna signals that correspond to said biological stimulus (col 9, Ins 44-56); a wireless reader for communication with said RFID tag and sensor module, said RFID reader being adapted to communicate information over a wireless network (Fig. 1, item 10; col 4, Ins 59-67; col 8, Ins 25-49); and a remote database associated with said network, said database containing information associated with said ID for reading and interpreting said sensor and for wireless retrieval by said wireless

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reader (col 4, Ins 7-20). While Crowley discloses an adhesive RFID tag attached to the skin of a patient, Crowley does not specifically disclose that the patch is flexible.

Nelson, on the other hand, discloses an adhesive, flexible RFID patch (col 4, Ins 66-67; col 5, Ins 1-5). It would have been obvious to one of ordinary skill in the art, at the time the invention was made to construct the RFID patch, disclosed by Crowley, with a flexible material, as disclosed by Nelson, so that the RFID patch will move freely on a non-planar surface such as a patient's skin (Crowley - col 9, Ins 5-10), while providing the patient optimal comfort of having a non-rigid, contoured structure attached to their skin. While Crowley discloses a reader for communication with said RFID tag and sensor module adapted to communicate information over a wireless network, Crowley does not disclose that the reader communicates through the use of multiple protocols with the RFID tag. Lu, however, discloses a multi-protocol wireless RFID reader for communication with a RFID tag (col 1, Ins 49-55; col 2, Ins 37-47). It would have been obvious to modify the reader of Crowley whereby it communicates through the use of multiple protocols (col 1, Ins 59-67), as disclosed by Lu, so that a single reader is used to communicate with multiple RFID tags, thereby providing an efficient system.

For claim 2, Crowley discloses a substantial portion of said RFID tag and sensor module is integrated onto a substrate disk (col 5, Ins 15-22; col 6, Ins 52-60).

For claim 3, Crowley discloses said substrate disk includes a protective layer attached thereto, said protective layer being in direct contact with the human skin when said patch is positioned on the human skin (Fig. 2, item 70; col 10, Ins 17-27).

For claim 4, Crowley discloses a sensor integrated with a layer that is adapted to react to said stimulus from a surface (i.e. body temperature of a human or animal; col 4, lns 32-67; col 5, lns 15-23). However, Crowley does not disclose that the protective layer is formed of a semi-permeable material. Nelson, on the other hand, discloses said protective layer is formed of a semi-permeable material (col 4, lns 56-67; col 5, lns 1-8). It would have been obvious to substitute a semi-permeable material, as disclosed by Nelson (i.e. fabric), for the protective layer of Crowley, to provide a patient with a breathable, wearable device for optimal comfort.

For claim 8, Crowley discloses stimulus sensing includes sensing at least one electrical, chemical, biological, and physical elements of said surface (col 1, lns 5-11).

For claim 9, Crowley discloses said RFID reader is selected from the group consisting of a cellular telephone, a personal digital assistant, a beeper, and a computer (Figs. 3 and 5, item 10; col 7, lns 30-34; col 8, lns 34-42).

For claim 11, Crowley discloses said RFID tag and sensor module further comprises a power unit adapted to stabilize voltage within said RFID tag and sensor module (col 8, lns 54-65; Fig. 1, items 46 and 50).

For claim 13, Crowley discloses an RFID tag and sensor formed as an integrated circuit (IC – col 5, lns 15-20; col 6, lns 46-51).

For claim 19, Crowley discloses said patch is disposable (col 3, lns 47-51).

For claim 20, Crowley discloses said RFID tag further includes a power generation module that powers said RFID tag (col 8, lns 13-15).

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3. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Ikefuji (US 5,774,062).

For claim 5, Crowley discloses a controller communicative with said sensor interface, said controller having a memory with a sensor data table being adapted to analyze said at least one sensor within said RFID tag and sensor module (col 5, lns 33-36 and 55-67; col 6, lns 1-12). Crowley, however, does not include a sensor interface having an analog to digital converter coupled to at least one sensor. Ikefuji, on the other hand, discloses a sensor interface having an analog to digital converter coupled to at least one sensor (Fig. 1, item 18; Fig. 6, A/D; col 8, lns 10-15). It would have been obvious to include an analog digital converter coupled to the sensor, as disclosed by Ikefuji, and interfaced with the controller of Crowley, so that an abundant amount of information from the sensor is sent back to the interrogator/reader via digital signals so that a diagnosis is made in a timely manner.

For claim 6, Crowley discloses said controller stores a sensor ID number in said sensor data table (col 4, lns 10-20).

For claim 7, Crowley discloses a temperature sensor communicative with said controller (col 6, lns 18-20).

4. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Valletta (US 6,970,105).

For claim 12, Crowley discloses a patch, but does not disclose a micro knife.

Valletta, on the other hand, discloses a micro knife located on a patch adapted to dispense a substance when said patch is pressed on said surface, where said surface is the skin of the person (col 1, Ins 43-49; col 3, Ins 31-40; Fig. 2, items 13, 18, 29). While Valletta does not specifically disclose that the micro knife (syringe) is used to draw blood from the surface of the skin, the examiner takes official notice that it is well known that the syringe may used to draw blood from the surface of the skin as well as apply a therapy as disclosed by Valletta. Furthermore, it would have been obvious to include the feature of draw blood from a patch worn by a patient, as disclosed by Valletta, and apply it to the patch worn by a patient, disclosed by Crowley, in order to closely monitor blood characteristics of a patient thereby providing the most appropriate treatment.

For claim 16, Crowley does not disclose a cardiac sensor. Valletta, on the other hand, discloses a cardiac sensor (col 1, Ins 47-50; col 3, Ins 1-5). It would have been obvious to detect cardiac throbs, as disclosed by Valletta, via a patch worn by a patient, disclosed by Crowley, in order to closely monitor the heart rate of a patient to determine exercise limitations of a patient.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Townsend et al. (US 6,529,127).

Crowley discloses an RFID tag, but does not disclose an RFID stress sensor. Townsend, however, discloses RF tag and sensor module includes at least one

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attachment point that enables attachment of the RF tag and sensor module to a structural stress, thereby forming a RF stress sensor (col 1, lns 25-47; col 2, lns 50-67; col 4, lns 8-27; Fig. 1, items 20a-20n). It would have been obvious to modify the RFID tag of Crowley to include a structural stress sensor disclosed by Townsend so that the integrity of a structure is maintained and confirmed as safe.

6. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Ghazarian (US 7,034,683).

Crowley discloses an RFID reader which includes a microprocessor adapted to analyze said patch, but Crowley does not disclose geolocating said patch. Ghazarian, however, discloses a reader that includes a processor adapted to analyze and geolocate a patch through the use of GPS (Fig. 1A, items 32, 40, and GPS; col 10, lns 37-50; col 17, lns 49-55). It would have been obvious to incorporate a GPS receiver as disclosed by Ghazarian into the reader disclosed by Crowley so that a tag or patch's location is accounted for at all times, such as during inventory control, tracking of individuals, etc..

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Lye et al. (US 2004/0100376).

Crowley discloses an RFID tag, but does not disclose a RFID sensor module integrated into an immunoassay testing strip. Lye, however, discloses a RFID sensor module integrated into an immunoassay testing strip (Fig. 3, item 12; parags 0164 and

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0165). It would have been obvious to include the RFID tag sensor module, disclosed by Crowley, integrated into an immunoassay testing strip, as disclosed by Lye, so that particular antigens are detected and communicated to a remote location for pharmaceutical purposes.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114), Nelson, Jr. (US 6,297,727) and Lu et al. (US 6,172,609), and further in view of Valletta (US 6,970,105) and Lye et al. (US 2004/0100376).

Crowley discloses a patch with a substrate, but does not disclose said patch having a sample input port enabling migration of an analyte by capillary forces; and at least one testing area integrated with said substrate area and adapted to capture antigens that flow through said testing area. Valetta discloses a sample input port enabling migration of an analyte by capillary forces; and at least one testing area integrated with said substrate area and adapted to capture data that flow through said testing area. While Valletta discloses capturing data that flow through said testing area, Valletta does not disclose that antigens flow through said testing area. Lye, however, discloses capturing data pertaining to antigens flowing through said testing area (parags. 0148, 0159, 0164, and 0165). It would have been obvious to modify the patch disclosed by Crowley with capturing data with an input port disclosed by Valletta, specifically focusing on capturing data pertaining to antigens disclosed by Lye so that data of a patient is captured and stored for future reference, such as data deviating from a predetermined range.

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9. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114) and further in view of Lu et al. (US 6,172,609).

For claim 25, Crowley discloses a human diagnostics system comprising: a patch having an RFID tag and sensor module (col 1, Ins 6-11; col 6, Ins 38-51), and adapted to be attached to the surface of the skin and adapted to sense at least one predetermined biological condition through the skin and transmit signals corresponding to at least one predetermined biological condition (col 4, Ins 36-50); a RFID reader communicative with said patch through the use of a network (col 10, Ins 37-40) to analyze, receive, and transmit the signals corresponding to said at least one predetermined biological condition from said patch (col 8, Ins 34-41; Fig. 1, items 10, 18, and 22); a remote storage and data unit communicative wirelessly with said RFID reader over said network (Figs. 1 and 5, item 10), said remote storage and data unit analyzing and storing biological data from said patch and said RFID (col 7, In 15) tag, said remote storage and data unit transmitting said analyzed and stored data to said RFID reader through the use of said network; and said remote storage and data unit further having a remote database containing information adapted to be wirelessly downloaded to said RFID reader for reading and interpreting said sensor (single reader for plurality of measurements/sensor tags downloaded to a database located on the reader – col 4, Ins 7-20; col 8, Ins 34-42; col 10, Ins 28-40). Crowley, however, does not disclose a RFID reader communicating to a tag through the use of multiple protocols. Lu, on the other hand, discloses a RFID reader communicating to a tag through the use of multiple protocols (col 1, Ins 49-55; col 2, Ins 37-47). It would have been obvious to

communicate through the use of multiple protocols with a RFID tag so that a single reader is used to communicate with multiple tags, thereby providing an efficient system.

For claim 26, Crowley discloses a remote wireless device (Fig. 5, item 10) adapted to remotely access said predetermined elements sensed by said RFID tag and sensor module (col 7, Ins 21-37; col 8, Ins 34-49).

For claim 27, Crowley discloses said predetermined elements include one or more electrical, chemical, biological, and physical element of a person (col 1, Ins 5-11).

10. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114) and Lu et al. (US 6,172,609) and further in view of Zeps et al. (US 6,937,154).

For claim 28, Crowley discloses a wireless network, but does not disclose communicating through the use of a communication protocol including, Bluetooth, Wi-Fi, Broadband, WLAN, and 3G. However, Zeps discloses communicating through the use of a communication protocol including, Bluetooth, Wi-Fi, Broadband, WLAN, and 3G (Fig. 1; col 9, Ins 30-67; col 10, Ins 33-42). It would have been obvious to communicate through the use of a communication protocol so that numerous equipment communicates with one another via a standardized communication channel.

For claim 29, Crowley discloses an RFID reader as a mobile, portable device, but does not disclose the RFID reader as a cellular telephone. Zeps, however, discloses the RFID reader as a cellular telephone (Fig. 1, items 31 and 34; col 3, Ins 33-45). It would have been obvious to design the reader as a cellular telephone so that the reader

is used for multiple purposes such as interrogating transponders and communicating with another during an emergency.

Response to Remarks

11. Applicant's arguments filed July 22, 2009 have been fully considered but they are not persuasive.

The Applicant argues as follows:

On page 14, the Applicant contends that Crowley cannot transmit information wirelessly with a remote database other than the RFID tag and that Crowley does not even mention the possibility of using a network for wirelessly transmitting and receiving information by the reader.

The Examiner responds by first alluding to the claim language (for claim 1 – also applicable to claim 25) “a diagnostic system comprising:... “a remote database associated with said network, said database containing information associated with said ID for reading and interpreting said sensor and for wireless retrieval by said wireless reader”. The remote database is in reference to a network wherein information (ID, sensor data) is retrieved wirelessly by the reader. Based on the Applicant's remarks, the Applicant is interpreting that the remote database is in reference to some other database separate from the reader/tag sensor system, however, the claim limitations are not so narrow and disclose no such thing. Therefore, the Examiner is interpreting the memory located within the tag sensor as the remote database (col 6, lns 52-67) since the reader extracts sensor information and ID from the tag's database for wireless

retrieval by the wireless reader. In addition, the reader can also be considered a remote database since the database is remote from the tag sensor and the reader's memory stores and compares data from either one or multiple tag sensors. Furthermore, the disclosure of Crowley is establishing a network (col 8, lns 25-32) by reading tags located on multiple patients (col 5, lns 37-45 and 56-65) and then downloading the information from the tags to a second computer database (col 4, lns 7-11).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). See MPEP § 706.07(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Mehmood whose telephone number is (571) 272.2976. The examiner can normally be reached on M-F from 8:00am to 4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Toan Pham, can be reached at (571) 272.2967. The fax phone number for the organization where this application or proceeding is assigned is (571) 273.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jennifer Mehmood/
Primary Examiner
September 9, 2009